UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

JIM CARR

AND

REBECCA CARR

Plaintiffs,

vs.

BIOMET ORTHOPEDICS, LLC, BIOMET, INC., BIOMET US RECONSTRUCTION, LLC, BIOMET MANUFACTURING, LLC F/K/A BIOMET MANUFACTURING CORP.

Defendants.

Case No.: _____

Hon. Judge: Robert L. Miller, Jr.

COMPLAINT WITH JURY TRIAL DEMAND ENDORSED HEREON

1. This is a product liability case involving a defective hip implant system. Plaintiff Jim Carr had a Biomet M2a 38 Metal-on-Metal Hip System[1] (hereafter, the "Device") implanted in his left hip. The Device suffers from defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the hip implant to fail and the surrounding tissue and bone to die.

PARTIES

2. Plaintiffs JIM CARR and REBECCA CARR are citizens of the State of Ohio and at all relevant times resided in the city of Sylvania, Ohio.

3. On information and belief, Defendant BIOMET ORTHOPEDICS, LLC, is a limited liability corporation organized and existing under the laws of the state of Indiana with its primary

[1] The M2a 38 Hip System that was implanted in Plaintiff was comprised of an M2a 38MM Acetabular Cup, Catalog No. RD118858, an M2a 38 Modular Head, Catalog No. 11-173661, and a lateralized stem, Catalog No. 11-104214.

place of business in Warsaw, Indiana. Biomet Orthopedics, LLC, designed, manufactured, marketed, promoted, and sold the Device that is the subject of this lawsuit. Biomet Orthopedics, LLC marketed, promoted, and sold the Device in Ohio.

4. On information and belief, Defendant BIOMET, INC., is a corporation organized and existing under the laws of the state of Indiana with its primary place of business in Warsaw, Indiana. Biomet, Inc. designed, manufactured, marketed, promoted, and sold the Device that is the subject of this lawsuit. Biomet, Inc. marketed, promoted, and sold the Device in Ohio.

5. On information and belief, Defendant BIOMET US RECONSTRUCTION, LLC, is a limited liability corporation organized and existing under the laws of the state of Indiana with its primary place of business in Warsaw, Indiana. Biomet US Reconstruction, LLC, designed, manufactured, marketed, promoted, and sold the Device that is the subject of this lawsuit. Biomet US Reconstruction, LLC marketed, promoted, and sold the Device in Ohio.

6. On information and belief, Defendant BIOMET MANUFACTURING, LLC f/k/a BIOMET MANUFACTURING CORP., is a limited liability corporation organized and existing under the laws of the state of Indiana with its primary place of business in Warsaw, Indiana. Biomet Manufacturing Corp., designed, manufactured, marketed, promoted, and sold the Device that is the subject of this lawsuit. Biomet Manufacturing Corp. marketed, promoted, and sold the Device in Ohio.

7. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

8. Upon information and belief, at all times herein mentioned, the employees of all Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of

the Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such allegations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

9. This is a civil action of which this Court has original jurisdiction pursuant to 28 U.S.C. §1332 as there is complete diversity of citizenship between Plaintiffs and Defendants, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

10. Venue for this action lies in the United States District Court for the Northern District of Ohio, Western Division, because the Plaintiffs reside in this District and the wrongful acts upon which this lawsuit is based occurred, in part, in this District. Venue is also proper pursuant to 28 U.S.C. §1391(c) because Defendants are all corporations that have substantial, systematic, and continuous contacts in the Northern District of Ohio and they are all subject to personal jurisdiction in this District.

11. Plaintiffs state that but for the Order permitting direct filing into the Northern District of Indiana pursuant to this Court's 2/15/13 Case Management Order, Plaintiffs would have filed in the United States District Court for the Northern District of Ohio. Therefore, Plaintiffs respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the U.S. District Court for the Northern District of Ohio.

FACTUAL BACKGROUND

BIOMET M2a 38 HIP FACTS

12. The Device was developed in order to reconstruct human hip joints that are diseased due to conditions, such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

13. A total hip replacement implant device typically consists of four separate components: a femoral stem, a femoral head (or ball), a liner, and an acetabular shell (socket). Usually these components are made of metal and plastic.

14. The M2a 38 Hip Replacement System (Device) has only three components: a metal femoral head, a metal taper insert, and a metal acetabulum cup. The metal femoral head can be attached to a femoral stem to complete a total hip replacement. As a result of the use of metal in the ball, taper insert, and socket components, the device is referred to by the industry as a Metal-on-Metal ("MoM") Implant Device.

15. These devices were marketed with the claim that they would last much longer than the conventional hip implant with a polyethylene liner. Indeed, Defendants aggressively marketed the Device as having many advantages over other hip replacements or hip resurfacing systems.

16. Defendants promoted the Device as having many advantages over other hip replacements or hip resurfacing systems. Defendants advertised that "range of motion studies performed on the M2A-38 suggests an average of 154 degrees range of motion – this is more than any other metal-

on-metal system on the market", and that "the plasma spray porous coating is more than twice as resistant to cup displacement under rim load than other coatings."

17. When initially released, Defendants promoted the device as a metal-on-metal articulation achieving "maximum range of motion, stability, and minimal wear." They advertised that "the large 38mm bearing surface exhibits similar wear characteristics to that of the 28mm and the 32 mm metal-on-metal articulations, approximately 1/350th the wear of metal-on-polyethylene."

18. Even as other MoM devices came under scrutiny for their high rates of failure over the years, Defendants continued to falsely advertise the Device as a superior and safe device, citing biased and misleading studies and data indicating that the hip replacement was subject to reduced wear and revision.

19. Contrary to what Defendants' marketing campaigns suggest, for many years Defendants have known of the risks inherent in MoM devices, including the M2a 38 Device, which were causing harm in a high number of patients who received them. Specifically, for several years, the FDA had been receiving complaints that the Devices prematurely failed in some patients, due to component loosening, dislocation, component wear, and fracture, as a result of the design of the device. In addition, reports were received that the implant's "ball" and "socket"—which are both metal bearings—generate metal debris over time from normal wear, and this debris can spread throughout the surrounding bone and tissue causing severe inflammation and damage.

20. Indeed, since the start of 2006, the FDA has received an increasing number of complaints involving patients in the United States that received the Devices, with a number of these patients requiring complicated, expensive and painful revision surgeries with a prolonged recovery time. Notwithstanding these complaints, Defendants neither halted sales of the Devices nor warned the

public. Instead, they continue to aggressively market the Device as safe and effective, even though they were on notice of the large number of complaints received by the FDA.

21. Defendants were aware that the British Medicines and Healthcare Products Regulatory Agency (**"**MHRA") and the United States Food and Drug Administration expressed concern about Metal-on-Metal hips and the impact of metal ions and thus, Defendants, as part of industry trade groups, participated in discussion of studies of the health effects with other manufacturers during that time period.

22. Defendants' reason to conceal the defect in its Device is clear. Hip implant sales are critically important to Defendants, and the Device is one of its most profitable products. During the time period relevant to this Complaint, Defendants' management was trying to make Defendants look appealing to investors, and in 2007, they were ultimately purchased by a private equity firm for $10 billion.

23. Defendants were faced with a critical defect in one of its most profitable hip implant systems. Rather than to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery, Defendants chose to pursue corporate profits, at the expense of patient safety, and continued to promote, market, and sell the Device despite the fact that they knew the product was defective. To this day, Defendants continue to sell these defective implants to unsuspecting patients with insufficient warnings about the risks or the failures that have been reported to the company.

24. In 2011, the Australian Orthopedic Association published its annual report on data collected from the Australian National Joint Registry, which tracks surgical revisions of orthopedic devices in Australia (the United States does not have such a registry). The Report showed that the Device had a yearly cumulative revision rate of 7.2% after seven years, with a

statistical range of 5.3% and 9.7%. This is a much higher revision rate than some other MoM hip replacements.

25. Consequently, in May of 2011, the FDA required Defendants, and other manufacturers, to provide data on levels of metal in the blood of patients implanted with their MoM hip implants due to rising concerns regarding their use. The request followed the release of British studies from March 2010 showing that MoM implants, such as the Device, are potentially dangerous because they can generate large amounts of metallic debris as they wear over time. Metallic debris has been shown to cause severe inflammatory responses in some patients, resulting in pain in the groin, death of tissue in the hip joint, and loss of surrounding bone. These injuries often require revision surgery to replace the device before its expected expiration.

26. In a systematic review of clinical trials, observational studies, and registries conducted by the FDA and published in the British Medical Journal on November 29, 2011, it was found that MoM hip implants are no more effective than traditional polyethylene-lined implants, and increase the risk of revision surgery. Therefore, MoM hip implants increase the safety risk to patients without providing any benefit over traditional hip implants. Due to this poor risk-benefit profile, sales of the Device have decreased substantially.

27. As a result of the issues with the Device, Plaintiff has suffered symptoms including pain, swelling, inflammation, and damage to surrounding bone and tissue, and lack of mobility. As noted above, these symptoms are the result of loosening of the implant, where the implant pulls away from the bone of the hip socket; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant that move against each other are no longer aligned; and the spread of metal debris generated from wear of the metal femoral head and metal acetabular cup. For these reasons, revision surgery is necessary to remove the defective Device.

Revision surgery presents enormous risks because it is technically more difficult than the original implanting surgery, the patient has an increased risk of complications and death, and the recovery time is prolonged and more painful than the recovery after the original implanting surgery.

PLAINTIFF FACTUAL ALLEGATIONS

28. During all material times, Plaintiffs have been residents of the state of Ohio.

29. On or about February 24, 2003, Plaintiff Jim Carr underwent a right total left replacement surgery performed by Dr. Karl J. Beer at The Toledo Hospital, Toledo, Ohio and received a M2a 38 Device.

30. Thereafter, Plaintiff suffered symptoms including but not limited to increasing pain, discomfort, dysfunction, soreness and loss of range of motion.

31. As a direct and proximate result of the failure of the defective M2a 38 Hip System, Plaintiff required a revision surgery on his left hip. This surgery to replace the failed Device was performed on October 25, 2013 by Dr. Karl J. Beer at The Toledo Hospital, Toledo, Ohio.

32. Upon information and belief, an employee and/or agent of Defendant provided the Device to Dr. Karl J. Beer who implanted the original Device.

33. Beyond merely providing the device to the surgeon, agents of Defendants were hired by Defendants to aggressively promote, distribute, and sell the Device.

34. Directors, managers, and sales representatives of Defendants received training and education from Defendants, including orthopedic and surgical training, product design rationale for the Device, education regarding proper use of the tools to implant the Device, selection of complementary components to the Device, and training on how to sell the Device to surgeons over hip replacements offered by competitors.

35. On numerous occasions, Defendants met with orthopedic surgeons to promote the Device. At some or all of these meetings, a representative or representatives of Biomet was present. During these meeting, Biomet assured the orthopedic surgeons that the Device was safe, effective, was the best product on the market, had an excellent track record, would last longer than traditional hip implants and had a low and acceptable failure rate. Biomet continued to "defend" the Device even after they became aware of numerous and serious complications with the Device. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

36. Plaintiff's revision surgery subjects him to much greater risks of future complications than he had before the revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

37. Had Plaintiff or Plaintiff's surgeon known that the Device caused injury and had the potential to require revision surgery to remove the device, with no benefit over traditional hip implants, then neither Plaintiff nor Plaintiff's surgeon would have chosen the Device for the hip

implant surgery. Rather, Plaintiff and Plaintiff's surgeon would have opted for the safer and more effective traditional hip implant utilizing a polyethylene liner.

38. As a direct and proximate result of the implantation of the Device, Plaintiff has suffered significant harm, including, but not limited to, physical injury and bodily impairment, debilitating lack of mobility and conscious pain and suffering. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

39. Plaintiff did not discover, nor did he have any reason to discover that his injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until Plaintiff was advised by his physician that his implant had failed and revision surgery was required.

40. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physician(s) the true risks associated with the use of the M2a 38 Hip Implant.

41. As a result of Defendants' actions, Plaintiff and his physician(s) were unaware, and could not reasonably have known or have learned through reasonable diligence, that he had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

COUNTS I-IV
Defective Manufacturing/Construction (O.R.C. § 2307.74)
Defective Design/Formulation (O.R.C. § 2307.75)
Defective Warning/Instruction (O.R.C. § 2307.76)
Defective Due to Nonconformity with Representation (O.R.C. § 2307.77)

42. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

43. At all times relevant to this action, Defendants were the manufacturers, as defined at Ohio Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the M2a 38 Hip System, which was placed into the stream of commerce.

44. At all times material hereto, the M2a 38 Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Defendants was expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff and Plaintiff's physician, without substantial change in the condition in which it was sold.

45. Defendants' M2a 38 Hip System was defective in its:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or

d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

46. Specifically, Defendants' failures, which permitted a defective product, Defendants' M2a 38 Hip System, to be placed into the stream of commerce, include, but are not necessarily limited to:

a. Defendants' failure to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control and/or distribution of the M2a 38 Hip System into interstate commerce in that Defendants knew or should have known that the M2a 38 Hip System was defective and subjected Plaintiff and others to risks, including the risk of premature failure requiring a complex, risky and painful surgery to remove and replace the defective product;

b. Defendants' failure to completely, accurately and in a timely fashion, disclose the risks of the M2a 38 Hip System, including the risk of premature failure and require a complex, risky and painful surgery to remove and replace the defective product;

c. Defendants' failure to conform with their representations to Plaintiff, Plaintiff's medical providers and/or agents, that the product was safe for the use for which it was intended, despite their actual and/or constructive knowledge that the M2a 38 Hip System was defective and subjected Plaintiff and others to risks, including the risk of premature failure requiring a complex, risky and painful surgery to remove and replace the defective product; and

d. Defendants' failure to sufficiently test the M2a 38 Hip System.

47. Plaintiff and Plaintiff's doctor used the M2a 38 Hip System as directed for its intended purpose.

48. The M2a 38 Hip System had not been materially altered or modified prior to its implantation in Plaintiff.

49. Defendants knew or should have known of the dangers associated with the use of the M2a 38 Hip System, as well as the defective nature of the M2a 38 Hip System. Despite this knowledge, Biomet continued to manufacture, sell, distribute, promote and supply the M2a 38 Hip System so as to maximize sales and profits at the expense of the public health and safety. Defendants' conduct was done in conscious disregard of the foreseeable harm caused by the M2a 38 Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

50. At all times herein mentioned, the M2a 38 Hip System was defective, and Defendants knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Plaintiff nor Plaintiff's physician knew or had reason to know of the existence of the aforementioned defects. Neither Plaintiff nor Plaintiff's physicians could have discovered the defects in the M2a 38 Hip System through the exercise of reasonable care.

51. Had Plaintiff or Plaintiff's surgeon known that the Device caused injury and had the potential to require revision surgery to remove the device, with no benefit over traditional hip

implants, then neither Plaintiff nor Plaintiff's surgeon would have chosen the Device for the hip implant surgery. Rather, Plaintiff and Plaintiff's surgeon would have opted for the safer and more effective traditional hip implant utilizing a polyethylene liner.

52. As a direct and proximate result of this defective M2a 38 Hip System, Plaintiff has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

53. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

54. The application of the Ohio Product Liability Act (Ohio Rev. Code § 2307.71, *et seq.*), particularly the determination of joint and several tort liability under R.C. § 2307.22, is inapplicable to the facts of this case, or, in the alternative, is unconstitutional in whole or in part based on the facts of this case.

Count V
Fraudulent Misrepresentation

55. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

56. Defendants, having undertaken the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control and/or distribution of the M2a 38 Hip System into interstate commerce, owed a duty not to deceive Plaintiff, Plaintiff's health care providers and the public regarding the testing, safety and efficacy of the M2a 38 Hip System.

57. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio R.C. § 2307.71 *et seq*.

58. As described herein, Defendants have fraudulently made specific misrepresentations and warranties as to the testing, safety and efficacy of the M2a 38 Hip System. As described above, the lack of a plastic, or other non-metal, acetabular liner causes excessive wear on the metal components allowing cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. These fragments also cause fluid accumulation and soft tissue and bone necrosis. Plaintiff believes that the fraudulent misrepresentations described herein were intentional to keep the sales volume of the M2a 38 and Magnum Hip System strong.

59. Upon information and belief, Defendants' fraudulent and specific misrepresentations concerning the testing, safety and efficacy of the M2a 38 Hip System have been made and/or published on multiple occasions in various forms of media, including, but not limited to, newspaper articles, ad campaigns, internet sites, data submissions, and/or promotional materials.

60. Defendants made the misrepresentations purposefully, willfully, wantonly and/or recklessly with the deliberate intent to deceive Plaintiff, Plaintiff's medical providers, the healthcare community and the public, and to cause medical providers and their patients to use the M2a 38 and Magnum Hip System.

61. At the time of Defendants' fraudulent misrepresentations, Plaintiff and Plaintiff's healthcare providers were unaware and ignorant of the deceptive statements and reasonably believed them to be true and relied upon them.

62. As a direct and proximate result of this conduct, the Plaintiffs have been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

63. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

64. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of the M2a 38 as described herein. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the Healthcare community and the general public.

Count VI
Loss of Consortium

65. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

66. As a direct and proximate result of Defendants' wrongful conduct detailed above, Plaintiff Rebecca Carr has suffered the loss of services, society, companionship, care, consideration, and assistance of Plaintiff, as well as mental anguish.

Count VII
Punitive Damages

67. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

68. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, Plaintiff's medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public, thereby entitling Plaintiff to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment for the following:

1. Past and future medical and incidental expenses, according to proof;
2. Past and future general damages, according to proof;
3. Punitive and exemplary damages in an amount to be determined at trial;
4. Prejudgment and post judgment interest;
5. Costs to bring this action; and
6. Such other and further relief as the court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demands a trial by jury as to all claims in this action.

Dated: 4/8/2014

Respectfully Submitted,

/s/ Michelle L. Kranz, Esq.
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